

CLAIMS

WHAT IS CLAIMED IS:

1. A method of characterizing the transfer of an analyte from a non-aqueous liquid composition to an aqueous medium, comprising the steps of:
 - 5 (a) providing a non-aqueous liquid composition comprising an analyte and a non-aqueous base;
 - (b) combining the non-aqueous liquid composition with an aqueous dissolution medium;
 - (c) agitating the non-aqueous liquid composition and the aqueous dissolution medium to form an emulsion; and
 - 10 (d) determining the amount of the analyte in the aqueous dissolution medium.
2. The method of claim 1, wherein in step (d) the amount of analyte in the aqueous dissolution medium is determined at more than one point in time.
- 15 3. The method of claim 1, further including a step of passing the aqueous dissolution medium, which is to be used for determining the amount of analyte in the aqueous dissolution medium, through a filter before determining the amount of analyte in the aqueous dissolution medium.
4. The method of claim 3, wherein the pore size of the filter ranges from about 0.1 to about 50 microns.
- 20 5. The method of claim 1, wherein the non-aqueous liquid composition is a pharmaceutical composition.
6. The method of claim 5, wherein the analyte is a pharmaceutically active component in the pharmaceutical composition.
- 25 7. The method of claim 5, wherein the pharmaceutical composition is a sustained release dosage form.
8. The method of claim 5, wherein the pharmaceutical composition further contains pharmaceutically acceptable components.

9. The method of claim 1, wherein the analyte is selected from ACE inhibitors; α -adrenergic agonists; α -adrenergic agonists; α -adrenergic blockers; α -adrenergic blockers (beta blockers); alcohol deterrents; aldose reductase inhibitors; aldosterone antagonists; amino acids; anabolics; analgesics (both
5 narcotic and non-narcotic); anesthetics; anorexics; antacids; anthelmintics; antiacne agents; antiallergics; antiandrogens; antianginal agents; antianxiety agents; antiarrhythmics; antiasthmatics; antibacterial agents and antibiotics; antialopecia and antibaldness agents; antiamebics; antibodies; anticholinergic drugs; anticoagulants and blood thinners; anticolitis drugs; anticonvulsants;
10 anticystitis drugs; antidepressants; antidiabetic agents; antidiarrheals; antidiuretics; antidotes; antiemetics; antiestrogens; antiflatulents; antifungal agents; antigens; antiglaucoma agents; antihistaminics; antihyperactives; antihyperlipoproteinemics; antihypertensives; antihyperthyroid agents; antihypotensives; antihypothyroid agents; anti-infectives; anti-inflammatories
15 (both steroidal and nonsteroidal); antimalarial agents; antimigraine agents; antineoplastics; antiobesity agents; antiparkinsonian agents and antidyskinetics; antipneumonia agents; antiprotozoal agents; antipruritics; antipsoriatics; antipsychotics; antipyretics; antirheumatics; antisecretory agents; anti-shock medications; antispasmodics; antithrombotics; antitumor
20 agents; antitussives; antiulceratives; antiviral agents; anxiolytics; bactericidins; bone densifiers; bronchodilators; calcium channel blockers; carbonic anhydrase inhibitors; cardiotonics and heart stimulants; chemotherapeutics; choleretics; cholinergics; chronic fatigue syndrome medications; CNS stimulants; coagulants; contraceptives; cystic fibrosis medications;
25 decongestants; diuretics; dopamine receptor agonists; dopamine receptor antagonists; enzymes; estrogens; expectorants; gastric hyperactivity medications; glucocorticoids; hemostatics; HMG CoA reductase inhibitors; hormones; hypnotics; immunomodulators; immunosuppressants; laxatives; medicaments for oral and periodontal diseases; miotics; monoamine oxidase
30 inhibitors; mucolytics; multiple sclerosis medications; muscle relaxants; mydriatics; narcotic antagonists; NMDA receptor antagonists; oligonucleotides; ophthalmic drugs; oxytocics; peptides, polypeptides and proteins; polysaccharides; progestogens; prostaglandins; protease inhibitors;

- respiratory stimulants; sedatives; serotonin uptake inhibitors; sex hormones including androgens; smoking cessation drugs; smooth muscle relaxants; smooth muscle stimulants; thrombolytics; tranquilizers; urinary acidifiers; urinary incontinence medications; vasodilators; vasoprotectants; and combinations thereof
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10. The method of claim 1, wherein the analyte is a cephalosporin.
11. The method of claim 1, wherein the analyte is ceftiofur, a pharmaceutically acceptable salt or derivative thereof.
12. The method of claim 1, wherein the non-aqueous base is a lipid.
- 10 13. The method of claim 12, wherein the non-aqueous base is an oil.
14. The method of claim 13, wherein the oil is selected from the group consisting of canola oil, coconut oil, corn oil, peanut oil, sesame oil, olive oil, palm oil, safflower oil, soybean oil, cottonseed oil, rapeseed oil, sunflower oil and mixtures thereof.
- 15 15. The method of claim 14, wherein the oil is cottonseed oil.
16. The method of claim 1, wherein the non-aqueous liquid composition is a suspension, solution or emulsion.
17. The method of claim 1, wherein the non-aqueous liquid composition is a suspension.
- 20 18. The method of claim 1, wherein the agitation is conducted until from about 10% to about 100% of the total amount of analyte, which was initially present in the non-aqueous liquid composition, has been dissolved in the aqueous dissolution medium.
- 25 19. The method of claim 1, wherein the aqueous dissolution medium comprises a buffer.
20. The method of claim 19, wherein the buffer is selected from the group consisting of glycine buffer, citrate buffer, acetate buffer, phosphate buffer, and borate buffer.

21. The method of claim 20, wherein the buffer has an optimal pH.
22. The method of claim 1, wherein the aqueous dissolution medium has an optimal pH.
24. The method of claim 1, wherein the aqueous dissolution medium is free of
5 surfactant.
25. The method of claim 21, wherein the aqueous dissolution medium is free of surfactant.
26. The method of claim 22, wherein the aqueous dissolution medium is free of surfactant.
- 10 27. The method of claim 1, wherein the aqueous dissolution medium comprises a surfactant.
28. The method of claim 1, wherein the ratio of non-aqueous liquid composition to aqueous dissolution medium by weight is from about 1 : 100 to about 1 : 2000.
29. The method of claim 1, wherein step (c) is carried out on a shaker.
- 15 30. The method of claim 29, wherein the shaker is a reciprocating shaker.
31. The method of claim 29, wherein the shaker has a stroke rate of from about 50 to about 400 cycles per minute.
32. The method of claims 1 or 29 wherein in step (c) the non-aqueous liquid composition and the aqueous dissolution medium are contained in a 40 mL
20 EPA type vial or a 50-100 mL serum type vial.
33. The method of claim 8, wherein the pharmaceutically acceptable component is selected from the group consisting of excipients, additives, suspending agents, preservatives, wetting agents, thickeners, buffers, flocculating agents, flavoring agents, sweeteners, colorants and fragrances.
- 25 34. The method of claim 10, wherein the cephalosporin is selected from the group consisting of ceftiofur, cefepime, cefixime, cefoperazone, cefotaxime,

cefpodoxime, ceftazidime, ceftizoxime, ceftriaxone, moxalactam, and pharmaceutically acceptable salts and derivatives thereof.

35. The method of claim 1 wherein the aqueous dissolution medium is selected from water, a hydrochloric acid solution, a simulated gastric fluid, a buffer solution, a simulated intestinal fluid, water containing a surfactant, a buffer solution containing a surfactant, and an aqueous alcoholic solution.
36. The method of claim 1 wherein the non-aqueous liquid composition is a suspension, solution, or dispersion.
37. The method of claim 1 provided that the non-aqueous liquid composition is not an emulsion.
38. A method of predicting the *in vivo* performance of a non-aqueous pharmaceutical composition comprising an analyte, said method comprising the step of characterizing the transfer of the analyte from the composition to an aqueous medium according to the method of claim 1.
39. A method of commercially producing and releasing a non-aqueous pharmaceutical composition comprising an analyte for public use, comprising the steps of:
- (a) preparing the non-aqueous pharmaceutical composition;
 - (b) characterizing the transfer of the analyte from the composition to an aqueous medium according to the method of claim 1; and
 - (c) confirming that the result from step (b) falls within desired standards.